JUDGE BATTS 10 CV 1020

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

HEATHER BROWER,

Plaintiff,

v.

GE HEALTHCARE, INC,
GE HEALTHCARE AS,
BAYER CORPORATION,
BAYER HEALTHCARE LLC,
BAYER PHARMACEUTICALS CORPORATION,
BAYER HEALTHCARE PHARMACEUTICALS, INC.,
BAYER SCHERING PHARMA AG,
SCHERING, AG,
SCHERING BERLIN, INC,
BAYER GESELLSCHAFT FUR BETEILIGUNGEN MBH,
BAYER AG,
MALLINCKRODT, INC.,
BRACCO DIAGNOSTIC INC.,
BRACCO RESEARCH USA, INC.,
ALTANA PHARMA AG,
NYCOMED INTERNATIONAL MANAGEMENT GMBH,

Defendants.

Case No.:

COMPLAINT

JURY DEMAND

COMPLAINT AND JURY DEMAND

Plaintiff Heather Brower, by and through her attorney, The Levensten Law Firm, P.C., and for her Complaint and Jury Demand against Defendants, alleges as follows:

1. This is an action for damages suffered by Plaintiff, as a direct and proximate result of the Defendants' wrongful conduct in connection with the manufacture, construction, design, formulation, preparation, assembly, testing, service, warning,

instruction, marketing, packaging, labeling, and/or supplying of their respective gadolinium based contrast dyes into the stream of interstate commerce.

2. At all times relevant and material, the GE Defendants were responsible for the manufacture, construction, design, formulation, preparation, assembly, testing, service, warning, instruction, marketing, packaging, labeling, and/or supplying of the gadolinium based contrast dye, Omniscan.

3. At all times relevant and material, the Bayer Defendants were responsible for the manufacture, construction, design, formulation, preparation, assembly, testing, service, warning, instruction, marketing, packaging, labeling, and/or supplying of the gadolinium based contrast dye, Magnevist.

4. At all times relevant and material, the Mallinckrodt Defendants were responsible for the manufacture, construction, design, formulation, preparation, assembly, testing, service, warning, instruction, marketing, packaging, labeling, and/or supplying of the gadolinium based contrast dye, OptiMARK.

5. At all times relevant and material, the Bracco Defendants were responsible for the manufacture, construction, design, formulation, preparation, assembly, testing, service, warning, instruction, marketing, packaging, labeling, and/or supplying of the gadolinium based contrast dyes, ProHance and MultiHance.

JURISDICTION AND VENUE

6. Plaintiff alleges an amount in controversy in excess of Seventy Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

8. The Court has personal jurisdiction over Defendants consistent with New York Law and the United States Constitution by virtue of Defendants' regularly conducted business in New York from which they derive substantial revenue.

9. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district.

PARTIES

10. At all times relevant hereto, Plaintiff Heather Brower was a resident citizen of the State of New York, and resides at 42 Wheeler Street in Deposit, NY 13754.

11. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey.

12. At all times relevant, Defendant GE Healthcare, Inc. was engaged in the business of manufacturing, constructing, designing, formulating, preparing, assembling, testing, servicing, labeling, marketing, packaging, supplying, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the drug Omniscan.

13. Defendant GE Healthcare, headquartered in the United Kingdom, is a unit of General Electric Company, and is further known as General Electric Company d/b/a GE Healthcare, and also doing business as GE Healthcare Medical Diagnostics, which is headquartered in Princeton, New Jersey.

14. At all times relevant and material, Defendant GE Healthcare, a/k/a General Electric Company d/b/a GE Healthcare, was engaged in the business of manufacturing, constructing, designing, formulating, preparing, assembling, testing, servicing, labeling, marketing, packaging, supplying, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the drug Omniscan.

15. Defendant GE Healthcare AS is a Norwegian corporation with its principal place of business in Norway. Defendant GE Healthcare AS is a subsidiary of General Electric Company.

16. Upon information and belief, the Omniscan that is currently distributed and sold in the United States by Defendant GE Healthcare, Inc. is manufactured by GE Healthcare AS.

17. Defendants GE Healthcare, GE Healthcare, Inc., and GE Healthcare AS have been and will be collectively referred to in this complaint as the GE Defendants.

18. At all times relevant and material, the GE Defendants were engaged in the business of manufacturing, constructing, designing, formulating, preparing, assembling, testing, servicing, labeling, marketing, packaging, supplying, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the drug Omniscan.

19. Defendant Bayer Corporation is an Indiana Corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania. Defendant Bayer Corporation is a resident and citizen of both Indiana and Pennsylvania.

20. Defendant Bayer Healthcare LLC is a Delaware limited liability company with its principal place of business in Wilmington, Delaware.

21. Defendant Bayer HealthCare LLC is a corporate successor to Berlex Laboratories, Inc. (Berlex) and as such is obligated for its predecessor's liabilities. Berlex was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Magnevist.

22. Defendant Bayer Pharmaceuticals Corporation is a division of Defendant Bayer Corporation. On January 1, 2008, Bayer Pharmaceuticals Corporation was merged into Bayer Healthcare Pharmaceuticals, Inc.

23. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 6 West Belt, Wayne, New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant is the U.S.-based pharmaceuticals unit of Bayer HealthCare L.L.C., and is a division of Bayer AG.

24. Defendant Bayer Healthcare Pharmaceuticals, Inc is a corporate successor to Berlex and as such is obligated for its predecessor's liabilities. Berlex was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Magnevist.

25. Defendant Bayer Schering Pharma AG is a foreign company domiciled in Germany.

26. Defendant Schering Berlin, Inc.'s principal place of business is 340 Changebridge Road, Montville, New Jersey. Schering Berlin, Inc. is wholly owned by Defendant Bayer Gesellschaft fur Beteiligungen mbH.

27. Defendant Schering AG is the predecessor to Defendant Bayer Schering Pharma AG and is a foreign company domiciled in Germany.

28. Prior to 2006, Berlex Laboratories, Inc. and Schering AG were engaged in the business of manufacturing, constructing, designing, formulating, preparing, assembling, testing, servicing, labeling, marketing, packaging, and/or supplying, either directly or indirectly through third parties or related entities, the prescription drug Magnevist.

29. Defendant Bayer AG bought Schering AG in 2006. Defendants Bayer Corporation, Bayer AG, Bayer Schering Pharma AG, Schering Berlin, Inc., Bayer Healthcare LLC, and Bayer Healthcare Pharmaceuticals, Inc. are corporate successors to Berlex Laboratories, Inc. and Schering AG, and as such are obligated for their predecessors' liabilities.

30. Defendant Bayer AG is a company domiciled in Germany and is the parent/holding company of all other Bayer Defendants including Defendant Bayer Gesellschaft fur Beteilingungen mbH.

31. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharmaceuticals Corporation, Bayer AG, Bayer Schering Pharma AG, Schering AG, Schering Berlin, Inc., Berlex Laboratories, Inc., and Bayer Gesellschaft fur Beteilingungen mbH will be collectively referred to in this Complaint as the Bayer Defendants.

32. At all times relevant and material, the Bayer Defendants were engaged in the business of manufacturing, constructing, designing, formulating, preparing, assembling, testing, servicing, labeling, marketing, packaging, supplying, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the drug Magnevist.

33. Defendant Mallinckrodt, Inc. is a Delaware corporation with its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri. Defendant Mallinckrodt, Inc. is a resident and citizen of both Delaware and Missouri.

34. At all times relevant and material, Defendant Mallinckrodt, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug OptiMARK.

35. At all times relevant and material, the Mallinckrodt Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug OptiMARK.

36. Defendant Bracco Diagnostic Inc. is a Delaware corporation with its principal place of business at 107 College Road East, Princeton, New Jersey. Defendant Bracco Diagnostic Inc. is a citizen of New Jersey and Delaware.

37. Upon information and belief, at all times relevant and material, Defendant Bracco Diagnostic Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate

commerce, either directly or indirectly through third parties or related entities, the prescription drugs MultiHance and ProHance.

38. Defendant Bracco Research USA, Inc. is a Delaware corporation with its principal place of business at 305 College Road East, Princeton, New Jersey. Defendant Bracco Research USA, Inc. is a citizen of New Jersey and Delaware.

39. Upon information and belief, at all times relevant and material, Defendant Bracco Research USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drugs MultiHance and ProHance.

40. Defendant Altana Pharma AG is a German company with its principal place of business in Germany. Defendant ALTANA Pharma AG manufactured MultiHance and/or ProHance for Bracco Industries, Inc.

41. Upon information and belief, at all times relevant and material, Defendant Altana Pharma AG was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drugs MultiHance and ProHance.

42. Defendant Nycomed International Management GmbH (Nycomed) is a Swiss company domiciled in Switzerland. Defendant Nycomed bought Defendant Altana Pharma AG in 2006. Defendant Nycomed is corporate successor to Altana Pharma AG and as such is obligated for its predecessors' liabilities.

43. Defendants Bracco Diagnostics Inc., Bracco Research USA, Inc., Altana Pharma AG and Nycomed will be collectively referred to in this Complaint as the Bracco Defendants.

44. At all times relevant and material, the Bracco Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of interstate commerce, either directly or indirectly through third parties or related entities, the prescription drugs MultiHance and ProHance.

GENERAL ALLEGATIONS

45. Omniscan is an injectable paramagnetic contrast agent for magnetic resonance imaging and arteriography. It contains the metal gadolinium which is highly toxic in its free state. Omniscan, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethylamide (gadodiamide), is represented by the GE Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

46. Magnevist is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It contains the metal gadolinium, which is highly toxic in its free state. Magnevist, the chemical name of which is gadopentetate dimeglumine, was represented by the Bayer Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of cranial and spinal anatomy as well as tumors, lesions, and immediately adjacent areas. Magnevist was further represented by the Bayer Defendants to be superior to two of their competitors (Omniscan and OptiMARK) in its thermodynamic and conditional stability, its low volume of excess chelate and its ability to prevent the release of gadolinium.

47. OptiMARK is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It contains the metal gadolinium, which is highly toxic in its free state. OptiMARK, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethoxyethylamide (gadoversetamide), is represented by the Mallinckrodt Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

48. Upon information and belief, MultiHance and ProHance are injectable paramagnetic contrast agents for magnetic resonance imaging and arteriography. They contain the metal gadolinium, which is highly toxic in its free state. Upon information and belief, MultiHance and ProHance were represented by the Bracco Defendants to be safely and effectively indicated for intravenous administration to facilitate visualization of lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues.

49. At all times relevant, Defendants knew or should have known that in its free state, gadolinium is highly toxic, harmful and dangerous to humans, and causes severe physical injury and knew or should have known of the need to prevent the gadolinium contained in its product from becoming free in the body of humans injected with Omniscan, Magnevist, OptiMARK, MultiHance, and/or ProHance through the use of, among other things, proper design, testing, and manufacturing.

PLAINTIFFS' INJURIES

50. Plaintiff Heather Brower, who has a history of renal insufficiency, was administered gadolinium based contrast agents.

51. Gadolinium is cleared from the body by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with gadolinium administration.

52. Neither Plaintiff, nor her prescribing physician, nor the performing radiologists or technicians were warned or cautioned by Defendants about the serious health risks presented by the administration of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

53. Subsequent to being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Plaintiff developed NSF/NFD, which was formally diagnosed, and progressed to widespread fibrosis in areas including, but not limited to, her arms, legs, and associated joints.

54. Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NFD), has been reported in medical literature for at least the last decade.

55. Prior to a decade ago, the group of symptoms now known as NSF/NFD had been variously described as scleromyxedema, scleroderma, or other connective tissue diseases. Regardless of the name ascribed to it, however, it has always been the case that this clinical entity now known as NSF/NFD develops only in patients with renal insufficiency whom have been given an injection of gadolinium-type contrast agent such as Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

56. NSF/NFD is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within days or weeks after receiving an injection of a gadolinium based contrast agent. These fibrotic and edematous changes produce muscular weakness

and inhibit flexion and extension of joints, resulting in contractures. NSF/NFD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF/NFD also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF/NFD is a progressive disease as to which there is no known cure.

57. The Defendants have consistently failed to warn consumers and/or their health care providers that NSF/NSD could result when the Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance is administered to patients with renal insufficiency.

58. As a direct and proximate result of being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Plaintiff suffered serious, progressive, incurable, and inevitably fatal injuries.

59. Defendants knew or should have known that the administration of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance to patients with renal insufficiency created an increased risk to those consumers of serious personal injury and even death.

60. Therefore, at the time Plaintiff was administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Defendants knew or should have known that the use of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance created an increased risk of serious personal injury, or even death to consumers with renal insufficiency.

61. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Defendants failed to warn Plaintiff and/or her health care providers of those serious risks.

62. Had Plaintiff and/or her health care providers known the risks of damages associated with Omniscan he would not have been administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance and would not have been afflicted with NSF/NFD.

63. As a direct and proximate result Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, she has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including, but not limited to, suffering from NSF/NFD, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which lead to her death.

64. Further, as a direct and proximate result of he being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Plaintiff suffered significant mental anguish and emotional distress, physical limitations, pain, injury, damages, harm, and mental and emotional distress.

65. Plaintiffs also incurred medical expenses and other economic harm as a result of Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

66. Despite reports of nephrogenic fibrotic changes and other data warranting caution and further evaluation, Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance

was marketed and sold without appropriate clinical evaluation of the nephrotoxic effect of this drug on patients with renal insufficiency, without appropriate clinical evaluation of the propensity of this drug to produce nephrogenic fibrosis in humans, and without appropriate and effective warning with respect to either.

67. At all times relevant hereto, Defendants knew or should have known about the significant health risk of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance administration to patients with renal insufficiency, including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs.

68. During the years that Defendants have manufactured, marketed, and sold Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, there have been numerous case reports, studies, assessments, papers, and other clinical data that have described and/or demonstrated NSF/NFD in connection with the use of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance. Despite this, Defendants have repeatedly failed to revise their package inserts, Material Safety Data Sheets, and other product-related literature, and to conduct appropriate post-marketing communications in order to convey adequate warnings.

69. In June 2006, and again in updated form in December 2006, the FDA issued Public Health Advisory Alerts concerning the development of serious, sometimes fatal, NSF/NFD following exposure to gadolinium-based contrast agents, including Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

70. The Defendants have repeatedly and consistently failed to advise consumers and/or their health care providers of the causal relationship between Omniscan,

Magnevist, OptiMARK, MultiHance and/or ProHance and NSF/NFD in patients with renal insufficiency.

71. The Defendants have failed to take prompt, reasonable, and effective measures to alert the appropriate members of the health care community and its patients, including, but not limited to, renal patients, nephrologists and other physicians, radiologists, administrators, technicians, and hospital/radiology supply personnel, to the serious adverse health risks presented by administration of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

COUNT I
Strict Products Liability
Defective Manufacturing

72. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

73. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

74. The Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury and death.

75. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiffs suffered serious physical injury, harm, damages and economic loss.

COUNT II
Strict Products Liability
Design Defect

76. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

77. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

78. The Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

79. The foreseeable risks associated with the design or formulation of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, include, but are not limited to, the fact that the design or formulation of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

80. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss.

COUNT III
Strict Products Liability
Defect Due to Inadequate Warning

81. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

82. The Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

83. The Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

84. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss.

COUNT IV
Strict Products Liability
Defect Due to Nonconformance with Representations

85. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

86. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance and made representations regarding the character or quality of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, including representations that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was safe.

87. The Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

88. Plaintiff and/or her health care providers justifiably relied upon Defendants' representations regarding the Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance at the time it was administered to him.

89. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance and the reliance on Defendants' representations regarding the character and quality of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT V
Strict Products Liability
Defect Due to Failure to Adequately Test

90. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

91. Defendants advised consumers and the medical community that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance were safe for use. Defendants failed to adequately test Omniscan with respect to its use by consumers with renal insufficiency.

92. Had Defendants adequately tested the safety of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance for use by consumers with renal insufficiency and disclosed those results to the medical community or the public, Plaintiff would not have been administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

93. As a direct and proximate result of Defendants' failure to adequately test the safety of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance and as a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT VI
Strict Liability in Tort

94. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

95. Defendants used and controlled toxic gadolinium for injection in humans.

96. Gadolinium is highly toxic, inherently dangerous, and ultrahzardous to humans.

97. Defendants allowed and directed that toxic gadolinium be used and injected in humans.

98. As a direct and proximate result of Defendants' use and control of toxic gadolinium, toxic gadolinium was injected and released into the body of Plaintiff and she suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

99. Defendants are strictly liable for Plaintiff's injuries, damages and losses.

COUNT VII
Negligence - Highest Possible Duty of Care

100. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

101. Because gadolinium is highly toxic and inherently dangerous and ultrahazardous to humans, Defendants had a duty to exercise the highest possible degree of care in the design, manufacture, sale and/or distribution of their respective product into the stream of commerce, including the duty to assure that their product did not pose a significantly increased risk of bodily harm and adverse events.

102. Defendants failed to exercise the highest possible degree of care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance into interstate commerce in that Defendants knew or should have known that the product was inherently dangerous and ultrahazardous to humans and caused such significant bodily harm or death and was not safe for administration to consumers.

103. Defendants also failed to exercise the highest possible degree of care in the labeling of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance and failed to issue to consumers and/or their health care providers, adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

104. Despite the fact that Defendants knew or should have known that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance posed a serious risk of bodily harm to consumers and was inherently dangerous and ultrahazardous to humans and particularly those with renal insufficiency, Defendants continued to manufacture and market their respective products for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

105. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise the highest possible degree of care as described above.

106. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT VIII
Negligence

107. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

108. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance

into the stream of commerce, including a duty to assure that their product did not pose a significantly increased risk of bodily harm and adverse events.

109. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for administration to consumers.

110. Defendants also failed to exercise ordinary care in the labeling of their respective products, and issuance of adequate warnings for Magnevist, OptiMARK, MultiHance and/or ProHance and failed to issue to consumers and/or their health care providers (including Plaintiff and her physicians) adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance. Had adequate warning been issued, and had Defendants' sales representative not made misleading statements concerning the contrast, Plaintiff and her physicians would not have permitted the contract to be used in her procedures.

111. Despite the fact that Defendants knew or should have known that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market their respective products for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

112. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

113. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT IX
Breach of Express Warranty

114. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

115. Defendants expressly warranted that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was/were a safe and effective paramagnetic contrast agent for magnetic resonance imaging.

116. The Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when administered in recommended dosages.

117. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT X
Breach of Implied Warranty

118. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

119. At the time Defendants designed, manufactured, marketed, sold, and distributed Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, Defendants knew of the use for which their respective product was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

120. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

121. Contrary to such implied warranty, Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was not of merchantable quality or safe for its intended use because the product was unreasonably dangerous as described above.

122. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT XI
Fraud/Misrepresentation

123. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

124. Defendants knowingly and intentionally made material, false and misleading representations to Plaintiff, her physician and to the public that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was safe for use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

125. Defendants' representations were in fact false, as Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance is not safe for use and its labeling, marketing and promotion did not fully describe all known risks of the product.

126. Defendants had actual knowledge based upon studies, published reports and clinical experience that their product, Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

127. Defendants knowingly and intentionally omitted this information in their product labeling marketing, and promotion and instead, labeled, promoted and marketed their product as safe for use in order to avoid monetary losses and in order to sustain profits in its sales to consumers.

128. When Defendants made these representations that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was safe for use, it knowingly and intentionally concealed and withheld from Plaintiff, her physician and the public the true facts that their respective product is not safe for use in consumers with renal insufficiency.

129. Defendants had a duty to disclose to Plaintiff, her physician and the public that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was not safe for use in patients with renal insufficiency in that it causes NSF/NFD because it had superior knowledge of these facts that were material to Plaintiff and her physician's decision to use Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

130. Plaintiff and her physician reasonably and justifiably relied on the Defendants' concealment of the true facts and reasonably and justifiably relied upon Defendants'

representations to Plaintiff and/or her health care providers that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was safe for human consumption and/or use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

131. Had Plaintiff and her physician known of Defendants' concealment of the true facts that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was not safe for human use, Plaintiff would not have been administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

132. As a direct and proximate result of Defendants' misrepresentations and concealment which were relied upon by Plaintiff and her physicians, Plaintiff was administered Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT XII
Negligent Misrepresentation

133. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

134. Defendants, in the course of their business profession, supplied Plaintiff and her physician with false information for guidance in their decision to use Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance.

135. The false information supplied by Defendants to Plaintiff and her physician was that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was safe and would not adversely affect Plaintiff's health.

136. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and her physician.

137. The false information obtained and communicated by Defendants to Plaintiff and her physician was material and they justifiably relied in good faith on the information to their detriment.

138. As a result of the negligent misrepresentations of Defendants which were relied upon by Plaintiff and her physicians, Plaintiff suffered injuries, damages and losses as alleged herein.

COUNT XIII
Outrageous Conduct

139. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

140. Defendants' concealment from Plaintiff and her physician that Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance was not safe for use was extreme and outrageous conduct in that such conduct is so outrageous in character and so extreme in degree that it goes beyond all possible bounds of decency and is atrocious and utterly intolerable in a civilized community.

141. As a direct and proximate result of Defendants' extreme and outrageous conduct, Plaintiff suffered and continues to suffer severe emotional distress.

142. As a result of Defendants' outrageous conduct, Plaintiff suffered and continues to suffer injuries, damages and losses as alleged herein.

COUNT XIV
Punitive Damages

143. The Plaintiff is entitled to punitive damages because of the Defendants' failure to warn was reckless and without regard for the public's safety and welfare. The Defendants misled both the medical community and the public at large, including the Plaintiff, by making false representations about the safety of their product. The Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of Omniscan, Magnevist, OptiMARK, MultiHance and/or ProHance, despite available information demonstrating the product was likely to cause serious, fatal side effects to its users.

144. The Defendants were or should have been in possession of evidence demonstrating that their product caused serious side effects. Nevertheless, they continued to market the product by providing false and misleading information with regard to its safety and efficacy.

145. The Defendants' actions, as described above, were performed willfully, intentionally, and with reckless and wanton disregard for the rights of the Plaintiff and the public. As a result of the Defendants' conduct, the Plaintiff suffered the injuries and damages specified herein.

146. Accordingly, Plaintiff seeks and is entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Medical expenses, income, and other economic damages in an amount to be determined at trial of this action;

3. Punitive damages;

4. Pre- and post-judgment interest;

5. Attorneys' fees, expenses, and costs of this action as allowed by law; and

6. Such further relief as the Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted this 4th Day of February, 2010.

THE LEVENSTEN LAW FIRM, P.C.

By: /s/ EP0405

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